K081439

JUN 17 2008

510(k) SUMMARY

VITOSS® BIOACTIVE FOAM and VITOSS® BIOACTIVE FOAM PACK BONE GRAFT SUBSTITUTES

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Orthovita, Inc.
45 Great Valley Parkway
Malvern, PA 19355

Phone: (610) 640-1775

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Contact Person: David J. McIlhenny
Sr. V.P., Operations

Date Prepared: May 21, 2008

Common or Usual Name – Vitoss® Bone Graft Substitute- Bioactive Foam Pack, Vitoss® BA Pack Bone Graft Substitute, Bone Graft Substitute

Classification Name – Bone Void Filler

Product Code - MQV

Predicate Devices

Orthovita, Inc. – Vitoss Bioactive Foam Bone Graft Substitute (K072184)

Intended Use / Indications for Use

Vitoss® Bioactive Foam Bone Graft Substitute- STRIP and PACK are labeled with the following Intended Use statement and are labeled with the following Indications for Use statement:

> Vitoss® Bioactive Foam Bone Graft Substitute is intended for use as a bone void filler for voids or gaps that are not intrinsic to the stability of the bony structure. Vitoss® Bioactive Foam Bone Graft Substitute is indicated for use in the treatment of surgically created osseous defects or

osseous defects created from traumatic injury to the bone. Vitoss® Bioactive Foam should not be used to treat large defects that in the surgeon's opinion would fail to heal spontaneously.

Vitoss® Bioactive Foam Bone Graft Substitute is intended to be used for filling bony voids or gaps of the skeletal system (i.e., the extremities, spine and pelvis). Following placement in the bony void or gap, the scaffold resorbs and is replaced with bone during the healing process.

Device Description

Vitoss Bioactive Foam and Vitoss Bioactive Foam Pack are resorbable, osteoconductive implants with a trabecular structure that resembles the multidirectional interconnected porosity of human cancellous bone.

Performance Data

Performance testing was conducted to ensure that Vitoss Bioactive Foam and Vitoss Bioactive Foam Pack met the predetermined design specifications. In all instances, Vitoss Bioactive Foam and Vitoss Bioactive Foam Pack functioned as intended.

Vitoss Bioactive Foam and Vitoss Bioactive Foam Pack are osteostimulatory based on in-vitro studies in which calcium phosphate growth was induced on the surface of the Vitoss Bioactive Foam and Vitoss Bioactive Foam Pack after exposure to simulated body fluid. This phenomenon was not observed in control samples in which there was no bioactive glass component. The osteostimulatory nature of Vitoss Bioactive Foam and Vitoss Bioactive Foam Pack has not been correlated to human clinical experience.

Substantial Equivalence

Vitoss Bioactive Foam Pack, subject of the Special 510(k), is a product line extension to the Vitoss Bioactive Foam product line. Vitoss Bioactive Foam Pack has the same intended uses and indications, technological characteristics, and principles of operation as its predicate device. The minor differences between Vitoss Bioactive Foam Pack and the predicate device raise no new issues of safety or effectiveness. Thus, Vitoss Bioactive Foam Pack is substantially equivalent to Vitoss Bioactive Foam.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 17 2008

Orthovita, Inc
% Mr. David J. McIlhenny
Senior Vice President Operations
45 Great Valley Parkway
Malvern, Pennsylvania 19355

Re: K081439
Trade/Device Name: Vitoss® Bioactive Foam Bone Graft Substitute-STRIP and PACK
Regulation Number: 21 CFR 888.3045
Regulation Names: Resorbable calcium salt bone void filler device
Regulatory Class: II
Product Code: MQV
Dated: May 21, 2008
Received: May 22, 2008

Dear Mr. Gilbert:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K081439

Device Name: Vitoss® Bioactive Foam Bone Graft Substitute- STRIP and PACK

Intended Use/Indications for Use:

Vitoss® Bioactive Foam Bone Graft Substitute is intended for use as a bone void filler for voids or gaps that are not intrinsic to the stability of the bony structure. Vitoss® Bioactive Foam Bone Graft Substitute is indicated for use in the treatment of surgically created osseous defects or osseous defects created from traumatic injury to the bone. Vitoss® Bioactive Foam should not be used to treat large defects that in the surgeon's opinion would fail to heal spontaneously.

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nilay D. Shah for

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K081439